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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,670	12/19/2005	Franco Macchi	207,380	5848

7590 07/07/2010

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EXAMINER	
BLAND, LAYLA D	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
07/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,670	MACCHI, FRANCO	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

This Office Action is in response to Applicant's request for continued examination (RCE) filed April 20, 2010, and response to the Final Office Action (mailed October 21, 2009), filed April 20, 2010.

Claims 7-13 are pending and are examined on the merits herein.

The following rejection of record is maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Schiena (EP 0444492, April 9, 1991, PTO-1449 submitted May 3, 2007) in view of Saxen et al. (Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1997; 84:356-61, of record).

Di Schiena teaches pharmaceutical compositions comprising 0.2 to 10% sodium hyaluronate having molecular weight between 800,000-4,000,000, preferably 1,000,000-2,000,000 [page 2, line 52] for the treatment and prophylaxis of inflammatory affections of the oral cavity [claims 1-10].

Di Schiena does not exemplify the treatment of recurrent oral aphthous ulcers using the composition.

Saxen teaches that recurrent aphthous ulcers are a common disorder, causing pain derived from inflammatory sensitization of nerve endings, and the most common treatment is topical anesthetics and topical steroids for pain management [page 356, first two paragraphs]. Adults having aphthous ulcers were treated with 3% diclofenac in 2.5% hyaluronan, 2.5% hyaluronan, or 3% viscous lidocaine. A 48% reduction in pain was observed 10 minutes after application with no significant difference between the three topical agents [see abstract]. Ulcers were smaller after treatment with HA [page 359, Table 1]. The blunting action of hyaluronan may be due to the coating action over the ulcer [page 360, second full paragraph], and the protective layering of the ulcer was a significant component of the overall treatment effect [page 360, third full paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Di Schiena's composition for the treatment of recurrent aphthous ulcers. Di Schiena teaches that HA of molecular weight 1,000,000-2,000,000 is useful for treating inflammatory affections of the oral cavity, including stomatitis, but does not specifically mention recurrent aphthous ulcers. Saxen teaches that HA alone can be used to treat recurrent aphthous ulcers, resulting in a reduction in pain and

smaller ulcers, but is silent with respect to the molecular weight of the HA. The skilled artisan could expect that Di Schiena's composition would be useful for the treatment of a specific inflammatory affection of the oral cavity, recurrent oral aphthous ulcers, because Saxen teaches that HA is effective for treatment of recurrent oral aphthous ulcers. The skilled artisan could expect that HA of molecular weight 1,000,000-2,000,000 could be effectively used in the method taught by Saxen because Di Schiena teaches that HA of that molecular weight is useful for treatment of inflammatory conditions of the mouth. Thus, the claimed invention is obvious over the prior art.

Response to Arguments

Applicant argues that Saxen shows that HA is inferior to diclofenac/HA, and that HA is only used for immediate pain relief. Thus, Applicant argues, the skilled artisan would not use HA for the treatment of ROAU. This argument is not persuasive because the skilled artisan would use HA for immediate pain relief. Although diclofenac/HA is superior for long-term pain relief, HA was effective for spontaneous pain relief, as shown in Saxen Figure 2. See MPEP 2123: "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments." *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971), and "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). It is also noted that the obviousness rejection is not based on the teachings of Saxen alone. Di

Schiena teaches that HA is used for the treatment of inflammations of the oral cavity. ROAU is an inflammatory condition of the oral cavity, as taught by Saxen.

Applicant argues that the group treated with HA was only a comparison and that the skilled artisan would have reasoned that no results could be achieved by using HA. This argument is not persuasive because Saxen clearly teaches immediate pain relief using HA. Furthermore, Di Schiena teaches that HA can be used for the treatment of oral inflammations and ROAU is an oral inflammation.

Applicant argues that the lesion sizes given by Saxen are not significant because the p value is large, and that Saxen teaches that no significant change in ulcer diameter or appearance was observed. Applicant's argument is noted. However, even if the skilled artisan were to completely discount the data in Table I, the prior art clearly suggests the use of HA for treating inflammations of the oral cavity and ROAU specifically. Even if Saxen is interpreted to suggest only immediate pain relief, pain management is the common treatment for ROAU, as taught by Saxen.

Applicant argues that the experiment described in Annex 1 shows that the sole active ingredient HA can be used to treat ROAU, which is unexpected in view of Saxen. This argument is not persuasive because the skilled artisan would expect that HA could be used to treat ROAU. Di Schiena teaches that HA can be used as the active principle for topical administration in the treatment and prophylaxis of inflammatory effections of the oral cavity [page 2, lines 47-53]. This is in contrast to the prior art, which teaches HA as only a vehicle [page 2, lines 25-28]. HA favors connective organization, opposes inflammatory process, and accelerates tissue repair processes [page 2, lines 15-19].

Saxen also teaches that HA binds to the adhesion molecules in the ulcers, forming a reservoir at the site of inflammation [page 360, column 1, last 2 paragraphs]. Furthermore, it is noted that the reduction of ulcers mentioned by Applicant did not occur until after several days of treatment. Saxen only studied the effects of HA over several hours, not days, and so cannot provide a "directly contrary teaching" with respect to numbers of ulcers as argued by Applicant.

For these reasons, the rejection is maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623